

specification with the Amendment and Reply filed September 13, 2006 to ensure the text of record matches with the text used by the Examiner.

Examiner Gucker indicated that, in his opinion, there were three issues which would have to be overcome, if a patent were to be granted: (1) Was the full scope of the proposed claims supported in the specification, (2) Did any of the amendments introduce new matter into the application, and (3) Was the claimed subject matter patentable over the two cited references?

1. Scope. This issue is tied to the identity of the agent administered in the claimed method. We discussed the “means-plus-function” language in proposed claims which should be limited to the structures disclosed in the specifications and their equivalents. Examiner Gucker said that he would be willing to consider such claims.

2. New Matter. Examiner Gucker agreed that the specification did disclose that galanin could “stimulate regeneration of sensory nerve axons”, but questioned whether any language in the specification could support a claim limitation to an aspect of the regeneration process which occurred more than 30 minutes after either injury or administration of galanin. I suggested addressing the issue by adopting claims from the draft proposal with limitations that include the phrase “rate of regeneration”. Examiner Gucker said that he would be willing to consider such claims (which were consequently submitted on September 13, 2006).

3. Patentability. Examiner Gucker explained his maintenance of the rejection for anticipation over Luo, et al., by pointing out that Luo discloses administration of galanin to the same patient population (nerve-damaged individuals), and thus the steps of the method are anticipated. The current record includes declaratory evidence that galanin’s stimulation of regeneration is unexpected in view of the prior art disclosure of an analgesic effect (see Zigmond Decl. of June 1, 2005, ¶¶ 9 and 14, and Dickerson Decl. of October 31, 2005, ¶¶ 16-18). The specification supplies support for the significance of the result (see top of page 11, regarding the statistical significance of the reported 30-40% difference). Thus, proof of unexpected results is already in the record. It was agreed that a further Declaration by the Inventor explaining the evidence.

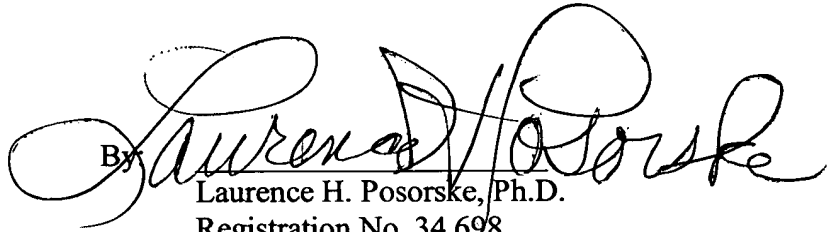
In summary, Examiner Gucker indicated that he was pleased that we had taken a new tack in the prosecution, and he felt that the case had been advanced. He would consider our claim amendments and arguments encouraging us to file an Amendment (with an RCE).

If there are any questions regarding this Interview Summary or the application in general, the Examiner is encouraged to contact the undersigned to expedite prosecution. No fees are believed to be due with the filing of this Interview Summary. However, in the event any fees are necessary, please charge such fees, including fees for any extensions of time, to the undersigned's **Deposit Account No. 50-0206**.

Respectfully submitted,

HUNTON & WILLIAMS LLP

Dated: September 15, 2006

By 
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